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Appl. No. : 10/022,996 Confirmation No. 4121
Applicants : Joseph R. Callol et al.
Filed : December 17, 2001
Art Unit : 3731
Examiner : Ryan J. Severson
Title : STENT FOR TREATING BIFURCATIONS AND
METHOD OF USE

Docket No.: : ACS 57812 (G2625P1)
Customer No. : 24201 April 20, 2009

Commissioner for Patents
P.O. Box 1450
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

The present invention relates to a method for treating a bifurcation in a body lumen. The claimed method calls for the mounting of a stent on a balloon catheter in a specified orientation and then advancing such assembly to a specified position relative to the bifurcation for deployment.

The present application, U.S. Serial No. 10/022,996 was filed on December 17, 2001.

NOTICE OF APPEAL

A Notice of Appeal from the Final Office Action of December 10, 2008 is being filed concurrently herewith with the appropriate fees.

ISSUE ON APPEAL

The claims all call for the stent to be mounted on a catheter having a long balloon and a short balloon wherein the balloons are positioned side by side **within** the stent and **adjacent** to its distal end. The method calls for such assembly to be advanced to the bifurcation such that **no portion of the stent is distal** to the side branch opening. The Examiner relies on a reference in which a complex multi-part bifurcated stent is advanced to a position in which each arm of the bifurcated stent extends well past the distal end of the side branch opening. The Examiner attempts to find anticipation by ignoring most of the stent's structure, misinterpreting the relative orientation of the catheter balloon and the remaining stent fragment, and ignoring the fact that the steps of the claimed method cannot logically be taken out of sequence.

ARGUMENT

Independent claims 8, 9 and 11-14 were rejected under 35 U.S.C. § 102(b) as anticipated by Dibié (WO 96/34580). The reference describes a stent 100 with three sections (110, 120, 140) that are interlinked by three connectors 130, 150 (page 3, lines 20-22) as is clearly illustrated in Figs. 1-4. A long balloon 210 is shown extending through two of the sections 110, 120 of the stent and a second balloon 230 is shown positioned exclusively within the third section 140 as is clearly illustrated in Fig. 5. The stent is then shown being advanced to the position illustrated in Fig. 6 wherein portions thereof are undeniably past the distal end of the opening to the side branch vessel. Anticipation is clearly avoided.

In an effort to find anticipation, the Examiner first ignores the description of the stent in the reference he is relying on. While the stent 100 is clearly described as having three sections, the Examiner instead characterizes the structure as being comprised of three stents that are interconnected. While such characterization provides for a much shorter stent, it does leave the second balloon 230 completely outside the newly defined "stent" as is apparent in Figs. 5 and 6.

The claims unequivocally call for **both** balloons to be positioned **within** the stent. In attempt overcome this inconvenient result, the Examiner then turns to the alternative embodiment balloon configuration shown in its inflated state in Fig. 10 in which the long balloon includes a recess 218 for accommodating the proximal end of the short balloon when such balloon is **angled** into a diverging branch vessel and **inflated** in an effort to find the proximal end of the short balloon to be "at least partially within the stent." Notwithstanding the fact that stent must logically be mounted on the catheter in the manner specified in the claims **before** the assembly can be advanced to the bifurcation to assume the angled configuration and inflated state, the Examiner completely ignores the fact that the only way the short balloon can even assume such position within the recess is due to the **absence** of stent material beyond the chamfer 115. The stent section itself ends along that chamfer, so consequently even the proximal end of the balloon that is positioned within the recess would be distal to stent and cannot be "at least partially **within** the stent." It should also be noted that it would be impossible to cause the proximal end of the balloon be inserted into a position **within** the stent from its initial position outside of the stent (Fig. 5) as the stent is crimped onto the balloon and is therefore in intimate contact with therewith. The Examiner can't have it both ways, either (a) the stent of the reference includes all three sections 110, 120, 140 in which case the reference teaches advancing the stent well beyond the distal end of the side branch opening which is contrary to what is called for in the claims, or (b) the stent ends at the distal end of the proximal section 110 (along its chamfer 115), in which case the short balloon is not positioned **within** the stent and does not in any way participate in the expansion of the stent which is again contrary to what is called for in the claims.

The Examiner goes on to offer an alternate interpretation in which he asserts that both balloons will be located within the stent during retraction of the balloons **after** deployment of the stent. However, the patent claims are directed to a method that inherently requires the stent to be mounted on the balloons in the manner specified **before** the catheter mounted stent can be advanced through the vasculature to the specified position, the balloons inflated to expand the stent and subsequently deflated for retraction. In his alternate interpretation, the Examiner not only ignores the sequence in which the steps clearly must be performed but also ignores the essence of the limitation within the second step of independent claim 8 which unequivocally calls for the stent to be **mounted** on the catheter such that the balloons are within the stent. Retraction of the deflated balloons subsequent to stent deployment does not comprise a

"mounting" of the stent on the balloon catheter as is specified in the claims. It should also be noted that the Figs. 5 and 6 clearly show the tube 244 associated with the short balloon 230 to extend along the **exterior** of the stent section 110 which would preclude the short balloon from being retracted through the stent section. Difficulties with such arrangement notwithstanding, the cited reference nonetheless fails to teach even the Examiner's alternate interpretation.

In sum, anticipation of the claims is clearly avoided in view of the very different method of deployment that is dictated by the very different stent and balloon configuration that is taught by the cited reference. Accordingly, the rejections of the pending claims should be withdrawn.

Respectfully submitted,

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